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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspide	PC10915A	5154

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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,774	DE RASPIDE ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10 and 15-42* is/are rejected.

7)☒ Claim(s) *5 and 11-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment B, received by the Office August 20, 2003.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 6-10, and 15-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/06161 to Jackson *et al.*, in view of US Patent 5,112,621 to Stevens *et al.*.

Jackson *et al.* teach the use of eletriptan for the prevention of migraine recurrence, in a dual-, sustained-, delayed-, controlled-, or pulsed-release dosage form (abstract). Jackson *et al.* teach that both the hydrobromide salt and the hemisulfate form of eletriptan are known in the art (page 1, lines 9-13). Jackson *et al.* specifically teach that the formulation of their invention can be in a pulsed-release form, including the sigmoidal releasing pellets discussed in US Patent 5,112,621.

Stevens *et al.* (US Patent 5,112,621, referred to immediately above) teach a sustained release pharmaceutical composition which comprises microparticles comprising an active principle (abstract). Furthermore, said microparticles are coated with a coating mixture comprising ethyl cellulose and an acrylic resin made of a polymerizate of acrylic and methacrylic ester, wherein the resin contains trimethylammonium methacrylate chloride (abstract). Stevens *et al.* also teach that the uncoated microparticles may comprise excipients such as a diluent and a binder. The diluent may be microcrystalline cellulose, and the binder may be hydroxypropylmethyl cellulose(column 1, line 61 – column 2, line 2). Additionally, a plasticizer, such as triethyl citrate, may be included (column 2, line 8). Stevens *et al.* also teach that the microparticulates can be in a unit dosage form, such as a hard gelatin capsule (column 1, lines 49-51).

One of ordinary skill in the art would have been motivated to combine the teachings of Jackson *et al.* and Stevens *et al.*, as this is precisely what is discussed in the Jackson *et al.* reference. This reference clearly teaches to look to the Stevens *et al.* reference when a formulation with sigmoidal release is desired.

The above combination of references do not specifically teach the presence of lactose. Absent evidence to the contrary, the inclusion of a well known pharmaceutical excipient does not render patentability to the claims. The selection of a known material (such as lactose) based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. Any showing of unexpected results must be based solely upon the inclusion of lactose.

The above combination of references does not specifically teach Applicant's claimed particle size. However, absent a showing of criticality, the examiner does not find this to be a patentable distinction. Specifically, the combination of Jackson and Stevens teaches the same end result as that claimed by Applicant: a particulate composition, comprising eletriptan and excipients, with a coating, allowing for sigmoidal release. Therefore, the particular particle size does not appear to be critical to the success of the invention. Furthermore, the determination of particular particle sizes is within the skill of the ordinary worker as part of the process of normal optimization. Any unexpected results must be dependant solely upon the particular particle size.

The above combination of references do not teach the specific coating thickness of the coating. However, absent a showing of criticality, the examiner does not find this to be a patentable distinction. Specifically, the combination of Jackson and Stevens teaches the same end result as that claimed by Applicant: a particulate composition, comprising eletriptan and excipients, with a coating, allowing for sigmoidal release. Therefore, the particular thickness of the coating does not appear to be critical to the success of the invention. Furthermore, the determination of particular coating thicknesses is within the skill of the ordinary worker as part

of the process of normal optimization. Any unexpected results must be dependant solely upon the particular coating thickness.

The above combination of references teaches a formulation which allows for sigmoidal release, comprising Applicant's claimed active agent and Applicant's claimed coating material. The combination of references, however, does not specifically set forth the release pattern for the formulation. Applicant, in claims 20 , 21, 38, and 39, recites a specific release rate. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For the above reasons, one of ordinary skill in the art would have been motivated to combine the teachings of Jackson *et al.* and Stevens *et al.* to create a pharmaceutical formulation comprising eletriptan, excipients, and a coating material. The combination of references teaches the same end result as that claimed by Applicant: sigmoidal release and treatment of migraines. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 5 and 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
Patent Examiner
Art Unit 1615
November 3, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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